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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,546	10/30/2003	David W. Wynn	MCP-5015	7575

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
10/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,546	WYNN ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,8,9 and 11-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,9 and 11-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 8/9/07.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3,19,23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah et al (USPN 6,126,969 hereafter '969). The claims are drawn to a pharmaceutical dosage from comprising an immediate release portion and an extended release portion.

2. The '969 patent teaches a dosage form comprising an immediate release portion and an extended releasing portion (abstract). The dosage from comprises sweeteners and other excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col, 5, lin. 15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including acetaminophen (tables). The acetaminophen is present in each phase in a concentration of approximately 41.5 % (table 2). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage from, it is the position of the Examiner that such limitations are inherent features of the composition. Since the '969 patent discloses the same structural components of the instant claims, it is the position of the

Examiner that the release profile/therapeutic effectiveness of the '969 patent would inherently meet the limitations of the instant claims. For these reasons, these disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-4,8,9,11-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Bourke et al (USPN 5,637,320 hereafter '320). The claims are drawn to a liquid dosage from comprising in immediate release portion and an extended release portion, where the extended release portion is suspended in the immediate release portion. The extended release portion comprises a coating comprises a combination of polymers including enteric polymers.

6. As discussed above the '969 patent discloses a dosage from comprising both an immediate release and extended release portion. The extended release portion comprises a coating of enteric polymers, and is suggestive of a combination of polymers, but is silent to the specific polymer combinations and ratios of the instant claims. These combination and ratios

however are well within the level of skill in the art to obtain given the suggestion of the art, as shown in the '320 patent.

7. The '320 patent discloses an extended release naproxen (a common pain reliever) formulation comprises a coating comprising a combination of polymers (abstract). The polymers include Eudragit brand enteric polymers along with cellulose acetate (col. 5, lin. 50-60). The polymers are present in a ratio from 1:2 to 20:1 of water insoluble polymers to enteric polymers (*Ibid.*). The formulation has a release that lasts up to 24 hours (figure 1). The artisan would be motivated to include the extended release particles of the '320 into the formulation of the '969 in order to provide an improved pain relief regimen.

8. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however is not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

9. With these things in mind it is the position of the Examiner that one of ordinary skill in the art would be motivated to combine the extended release coated particles of the '320 patent into the combination release formulation of the '969 in order to improve and extend the pain relieving properties of the formulation. One of ordinary skill in the art would have been motivated to prepare a suspension as suggested by the '969 patent in order to provide relief to patient with difficulty swallowing. It would have been obvious to combine the teachings and

suggestions of the art with an expected result of a sustained release pain relief formulation along with a method of treating pain over a long period of time.

Response to Arguments

10. Applicant's arguments filed 8/9/07 have been fully considered but they are not persuasive. Applicant argues that:

a. The Shah reference does not disclose enteric polymers and does not anticipate the newly amended claims

b. As such the Shah reference does not obviate the instant claims.

11. Regarding argument a., it is the position of the Examiner that the Shah reference anticipates the claims. The Shah reference discloses a formulation comprising both immediate release and sustained release particles. The sustained release particles are coated with a combination of polymers and copolymers including water-insoluble and enteric polymers such as cellulose acetate phthalate (col. 4, lin. 60-68). The formulation can be dispersed in water to form a suspension useful for treating pain due to the use of acetaminophen. For these reasons at least the claims remain rejected.

12. Regarding argument b., it remains the position of the Examiner that the combination of the prior art continues to obviate the claims. As discussed above the Shah reference discloses a formulation comprising uncoated and coated particles comprising acetaminophen. The coated particles can comprise water insoluble and enteric polymers. The reference is however silent to a specific ratio do water-insoluble polymers to enteric polymers. The '320 patent provides an enterically coated particulate formulation comprising pain relievers where the coating

comprising the same enteric and water-soluble polymers of the instant claims in a similar ratio of water-insoluble: enteric polymers (col. 5, lin. 50-60). The skilled artisan would have been motivated to combine the coating of the '320 patent into the formulation of the '969 patent. The '969 patent discloses that the formulation comprises a combination of polymers, and the '320 patent provides the specific polymers in combination. An artisan would have been motivated to combine the teachings in order to provide a stable gastric release of the pain relieving formulation. For these reasons the claims remain obviated.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER